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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,369	02/26/2004	Shozo Koyama	AMN-006-003	3406
20374 7590 01/26/2007 KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER HAQ, SHAFIQUH	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/786,369	Applicant(s) KOYAMA ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-46 is/are pending in the application.
- 4a) Of the above claim(s) 29-34, 36 and 38-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/19/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

1. Applicants' election without traverse of Group IV, claims 35-37 filed December 6, 2006 in response to Office Action of October 6, 2006 is acknowledged and entered. Applicants' election of species (R₃, R₄, R₅ and R₆ are each a hydrogen atom) is also acknowledged. Claims 35 and 37 read of the elected species. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, claims 29-34, 36 and 38-46 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

2. Claims 35 and 37 are examined on merits.

Oath or Declaration

3. It is noted that PCT/JP98/00351 is recorded under "PRIOR FOREIGN APPLICATION(S)" in the declaration filed 2/26/04, however, a proper box (YES, NO) has not been checked for "PRIORITY CLAIMED UNDER 35 USC § 119".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 35 is directed to method of producing "an antigenic substance". However, it is unclear as to what is meant by this term. The nature of the antigenic substance is unclear. Is this a substance which is antigenic in nature and which is used to induced the production of antibodies? Is this "antigenic substance" is a hapten conjugated with a carrier, what specific epitope is the corresponding antibody reactive with?
7. Claim 35 recites the phrase "contacting cells of a biologically functioning substance". It is unclear as to what type of cells are encompassed by the term "cells of a biologically functioning substance" and what "functioning substances" are meant by "biologically functioning substance".
8. Claim 35 recites the phrase "isolating and/or separating components of the resultant extinguished cells to obtain the antigenic substance". The nature and structure of the antigenic components are unclear. It is unclear what "components of the resultant extinguished cells" are considered "antigenic substance". Is the resultant antigenic component a conjugate of the compound 3-a with a biological molecule of the cell?
9. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolation and separation steps of the antigenic components of resultant extinguished cells.

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10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to producing antigenic substances (assuming that antigenic substance is meant by substance that can induce antibody production) by contacting with a cell with the compound of formula 3-a and isolating and separating components of the extinguish cells that are antigenic. Subject matter was not described in the specification in such a way as to one of skilled in the art could reasonable tell which components of the extinguished cells are antigenic (i.e. induce antibody production) as the nature of the antigenic substance is not clearly described in the specification. Specification also does not describe how the antigenic components are isolated/separated from the rest of cell components that are not antigenic. Specification states the following in page 54, lines 26-27: "This invention indicated that a family of Yoshixol demonstrated in examples in this invention is a molecule of which becomes to be hapten". Lines 19-25 further states "hapten is a molecule of which is not able to induce an immuno response by itself. ----. Hapten becomes an antigen when it is linked with a carrier of adequate macromolecules." Specification discloses induction

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Yoshixol (page 40, lines 15-17) and increase of survival time by injecting culture media containing extinguished cells into animal having leukemia (page 41, lines 3-4). However, specification does not describe isolating/separating components that are antigenic from the extinguished cells and does not describe the nature of the components of the cell that is rendered antigenic by Yoshixol.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Koyoma et al. (US 6,710,090) disclose Yoshixol as inhibitor or blocker of molecular generating and inducing functions of molecules but do not disclose using Yoshixol for generating antigenic components from cells.

Koyoma et al. (US 6,346,551 B1) disclose Yoshixol as inhibitor or blocker of molecular generating and inducing functions of molecules but do not disclose using Yoshixol for generating antigenic components from cells.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



LONG V. LE 01/22/07
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